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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/886,711	06/21/2001	Christos J. Petropoulos	2793/65318/JPW/AJM/DRM	1782

7590 05/08/2002

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EXAMINER	
MOSHER, MARY	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 05/08/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/886,711	Petropoulos
Examiner	**Art Unit**
Mosher	1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *three* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *3/1/02* .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-55* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-55* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claim Objections

Claim 13 and 38 are objected to because of the following informalities: the claims are mising "is an" after "avian cell". Appropriate correction is required.

Claim 55 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim must depend from other claims only as alternatives. The claim requires step (b) to be done both according to claim 50 (because that is required by the parent claim) and according to claim 32. See MPEP § 608.01(n). Accordingly, the claim has not been further treated on the merits.

Specification

The following guidelines illustrate the preferred layout and content for patent applications. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

The following order or arrangement is preferred in framing the specification and, except for the reference to the drawings, each of the lettered items should appear in upper case, without underling or bold type, as section headings. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) Title of the Invention.
(b) Cross-Reference to Related Applications.
(c) Statement Regarding Federally Sponsored Research or Development.
(d) Reference to a "Sequence Listing," a table, or a computer program listing appendix submitted on compact disc (see 37 CFR 1.52(e)(5)).
(e) Background of the Invention.
    1. Field of the Invention.

2. Description of the Related Art including information disclosed under 37 CFR 1.97 and 1.98.

(f) Brief Summary of the Invention.
(g) Brief Description of the Several Views of the Drawing(s).
(h) Detailed Description of the Invention.
(i) Claim or Claims (commencing on a separate sheet).
(j) Abstract of the Disclosure (commencing on a separate sheet).
(k) Drawings.
(l) Sequence Listing, if on paper (see 37 CFR 1.821-1.825).

In the interest of compact prosecution, the following changes to the specification have been made by informal Examiner's amendment:

Table 1 has been renumbered as page 57.

The two pages of References have been renumbered as pages 58-59.

The Claims have been renum,bered as pages 60-70.

The Abstract has been renumbered as page 71.

Claim Rejections - 35 USC § 112

Claims 1-55 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claims in this application all require a hepadnavirus virion to be made infectious to cells where it normally is noninfectious (e.g. cultured cells), by incorporation of part or all of a foamy virus envelope protein. This method of changing the host range of a virus, by incorporating a foreign virus external protein, is oftern termed pseudotyping. The prior art recognizes that foamy virus envelope proteins can be used to pseudotype another retrovirus (see Lindemann et al

6,150,138) and VSV (see Hill et al, J. Gen. Virol. 80:2003-2009, 1999). However, the examiner was unable to find any prior art indicating sucessful pseudotyping of hepatitis B virus (HBV). Eastman et al (not prior art) indicates that it was known in the art that HBV and foamy viruses both require expression of the envelope protein for budding of intracellular capsids from the cell, and indicates that gag-env interactions are essential to drive budding of infectious particles. Since the prior art does not permit one to predict whether or not the HBV and FV gag and env proteins are able to interact with the heterologous protein, one skilled in the HBV art would have reason to doubt unsupported assertions regarding pseudotyping of HBV. While the specification contains detailed discussion of methods to use, the specification contains no working example where cell-culture-infectious HBV particles were actually produced. Considering the state of the art, the lack of a working example, and the unpredictability of sucess in producing an HBV pseudotype, it is concluded that undue experimentation would be required to make and use the invention as claimed. This rejection could be obviated by a showing of evidence that the methods taught in the specification actually do produce cell-culture-infectious hepadnavirus.

Conclusion

Claims 1-55 are free of the art. Lindemann et al 6,150,138 broadly teaches production of pseudotyped virus particles with foamy virus envelope protein, but does not teach or suggest hepadnaviruses as a species to pseudotype. Capon et al teaches screening methods for testing drug resistance in hepatitis B virus, but does not teach or suggest use of a foamy virus envelpe

protein. Hill et al teaches a pseudotyped VSV with foamy virus envelope protein, but does not teach or suggest hepadnaviruses.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. Mosher, Ph.D. whose telephone number is (703) 308-2926. The examiner can normally be reached on Monday -Thursday and alternate Fridays from 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027. The fax phone number for this Group is now (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

May 6, 2002

MARY E. MOSHER
PRIMARY EXAMINER
GROUP 1800
1600